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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,491	09/05/2003	Dagmar Beyerlein	5618.P3653	8370

7590 02/23/2006

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EXAMINER

HUH, BENJAMIN

ART UNIT PAPER NUMBER

3767

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b> 10/656,491	<b>Applicant(s)</b> BEYERLEIN, DAGMAR	
	<b>Examiner</b> Benjamin Huh	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/21/05 &amp; 9/5/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Invention I and Species I in the reply filed on 12/05/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (Patent No. 5396897) in view of Van Tassel et al (Patent No. 5292309). Jain et al discloses a system for "detecting tissue contact and penetration depth" comprising a needle (1,2) in figure 1A with a first end (4,5) and a second end which is not shown and a lumen extending therethrough (7) in which therethrough is defined as "there from one end or side to the other", the needle (1,2) having at least one aperture (3,8) communicable with said lumen and provided on said needle and located a predetermined distance from the first end (col. 6, line 65 – col. 7, line 3 & col. 8, lines

18-25); a pressure measurement assembly coupled with a portion of the needle to measure a fluid pressure flowing through the needle (col. 6, lines 55-59), the pressure measurement assembly measuring a first pressure before the aperture becomes occluded and a second pressure as the needle penetrates tissue and the aperture becomes occluded(claim 1). Even though Jain et al does not have a needle where the predetermined distance is used to specify a depth of the needle attention is directed to Van Tassel et al which discloses a "surgical depth measuring instrument and method". Van Tassel et al depicts a depth measuring device which has graduated markings (44) seen on figure 1 on the side wall of the tubular member (30) which can be used to "specify a depth of the needle" wherein the graduated markings are started from the location of the aperture (32). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the graduated markings from the Van Tassel reference to the device of Jain et al in order to determine the depth that the needle has been inserted so that the distance can be tracked.

With regards to claim 2, wherein said pressure measurement assembly comprises a fluid pressure sensor as seen as sensor tube 2 as found in Jain.

With regards to claim 3-4, the fluid pressure, which is a static pressure, includes a pressure of a therapeutic agent to be injected through the needle and into the tissue see col. 7, lines 20-35.

With regards to claim 5-7 & 9-10, see col. 6, line 65 – col. 7, line 3, & col. 8, lines 18-25.

With regards to claim 8, see the tapered and untapered portions of the needle in figures 1A & 1D.

With regards to claims 11-12, wherein the system further comprises a computer processor coupling configured to perform at least one of determining and distinguishing said rate of changes in said static pressure to determine and distinguish said various penetration depths of said needle and further couples to at least one of a visual feedback system indicator and an audible feedback system to issue human-recognizable signals as to penetration depths of said needle attention is directed to col.7 lines 20-35 in Jain.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (Patent No. 5396897) in view of Van Tassel et al (Patent No. 5292309) in further view of Clarke (US Pub. 2005/0027199A1) or Stoller et al (US Pub. 2004/0171933A1) or Freeman et al (US Pub. 2003/0083686A1). The Clarke, Stoller, and Freeman references all disclose a computer processor coupling to a measurement assembly configured to perform at least one of determining and distinguishing a rate of change in a parameter to determine and distinguish various penetration depths of a needle as well as at least one of a visual feedback system indicator and an audible feedback system to issue human-recognizable signals as to penetration depths of the needle and it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate one of the computer processors to determine the rate of change in the desired parameter, static pressure, in order to determine the penetration depth

more precisely and to incorporate a visual or audible feedback system in order to more easily recognize the penetration depth of the needle.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BHH



MICHAEL J. HAYES  
PRIMARY EXAMINER